

Sub A1
What is claimed is:

1. A method of providing direct blood flow between a heart chamber and a coronary vessel, the method comprising the steps of:
placing a guide device through an anterior wall and a posterior wall of the coronary vessel and through a heart wall between the heart chamber and the coronary vessel;
forming a passageway in the heart wall at a location defined by the guide device;
and
delivering a stent within the passageway via the guide device.
2. The method of claim 1, wherein forming the passageway includes providing a dilation mechanism at the location defined by the guide device.
3. The method of claim 2, wherein the dilation mechanism includes a sheath.
4. The method of claim 2, wherein forming the passageway further includes expanding the dilation mechanism.
5. The method of claim 4, wherein the expanding includes inflating the dilation mechanism.
6. *Sub A2* The method of claim 1, wherein the stent is a collapsible stent and delivering the stent in the passageway includes expanding the stent.
7. The method of claim 1, further comprising delivering via the guide device a first mechanism for forming the passageway and a second mechanism for placing the stent within the passageway.

FOR 50-1544850

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

8. The method of claim 7, wherein the first and second mechanisms are delivered via the guide device to the heart simultaneously.

9. The method of claim 7, wherein the first mechanism is delivered via the guide device to the heart and, after the first mechanism is removed from the heart via the guide device, the second mechanism is delivered via the guide device to the heart.

10. The method of claim 7, wherein the second mechanism includes a stop mechanism and the delivering the stent includes advancing the stent within the passageway until the stop mechanism engages one of a wall of the coronary vessel and a surface of the heart wall.

11. The method of claim 10, wherein the stent is advanced until the stop mechanism engages the posterior wall of the coronary vessel.

12. The method of claim 11, wherein the stop mechanism is located at substantially a proximal end of the stent during the delivery of the stent.

13. The method of claim 7, wherein the first mechanism includes a stop mechanism and delivering the first mechanism includes engaging the stop mechanism with at least one inner wall of the coronary vessel.

14. The method of claim 13, wherein engaging the stop mechanism includes expanding the stop mechanism.

15. The method of claim 1, further comprising measuring a distance from the anterior wall of the coronary vessel to the left ventricle prior to placing the guide device.

16. The method of claim 1, wherein the guide device is a guidewire.

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

0454-030
BB

17. The method of claim 1, further comprising the step of inserting a hollow needle through the anterior wall and the posterior wall of the coronary vessel and the heart wall, prior to placing the guide device.

18. The method of claim 17, wherein the guide device is a guidewire, and the step of placing the guide device includes inserting the guidewire through the hollow needle until an end of the guidewire rests in the heart chamber.

19. The method of claim 18, further comprising the step of removing the hollow needle after inserting the guidewire through the hollow needle.

20. The method of claim 17, further comprising the step of measuring a depth of insertion of the hollow needle.

21. The method of claim 20, wherein the measuring step includes viewing markings on the hollow needle, the markings indicating the depth of insertion of the hollow needle.

22. The method of claim 21, further comprising determining the thickness of the heart wall by subtracting a diameter of the coronary vessel from the distance measured by the needle, and selecting said stent based on the heart wall thickness.

23. The method of claim 17, further comprising avoiding intracardiac structures during insertion of the hollow needle.

24. The method of claim 1, further comprising placing the guide device at a predetermined angle relative to the posterior wall of the coronary vessel.

25. The method of claim 24, wherein placing the guide device at a predetermined angle includes inserting a hollow needle at the predetermined angle through the anterior

wall and the posterior wall of the coronary vessel and the heart wall, prior to placing the guide device.

26. The method of claim 1, wherein forming the passageway includes inserting a sheath into the location defined by the guide device.

27. The method of claim 1, wherein forming the passageway includes inserting a balloon into the location defined by the guide device and inflating the balloon.

28. The method of claim 27, wherein inserting the balloon includes inserting a catheter carrying the balloon over the guide device.

29. The method of claim 27, further comprising deflating the balloon after forming the passageway, and removing the balloon from the passageway after deflating the balloon.

30. The method of claim 1, wherein delivering the stent includes delivering the stent with an expansion device.

31. The method of claim 30, wherein the expansion device includes an inflation device.

32. The method of claim 31, wherein the inflation device is a balloon that carries the stent, and placing the stent includes inserting the balloon and the stent within the passageway and inflating the balloon.

33. The method of claim 32, wherein inserting the balloon and the stent includes inserting a catheter carrying the balloon and the stent over the guide device.

FOR "45454560"

Sub
A4

Sub
A5

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

45754860
P3

34. The method of claim 1, wherein the passageway is formed and the stent is delivered by a catheter carrying a first expansion device and a second expansion device.

35. The method of claim 34, wherein the first and second expansion devices include inflation devices.

36. The method of claim 35, wherein the first inflation device is a first balloon and the second inflation device is a second balloon.

37. The method of claim 36, further comprising inserting the catheter over the guide device so that the first balloon is positioned in the location.

38. The method of claim 37, further comprising inflating the first balloon to form the passageway.

39. The method of claim 38, further comprising deflating the first balloon after forming the passageway, and further inserting the catheter over the guide device so that the second balloon is positioned in the passageway.

40. The method of claim 39, wherein the second balloon carries a stent, and further comprising inflating the second balloon to place the stent within the passageway.

41. The method of claim 37, wherein the second balloon is positioned within the coronary vessel when the first balloon is positioned in the location.

42. The method of claim 41, further comprising inflating the second balloon so that the second balloon engages at least one interior wall of the coronary vessel and inflating the first balloon, the first balloon carrying the stent.

Sub
a6

43. The method of claim 1, wherein the delivering of the stent includes advancing the stent within the passageway until a stop mechanism engages the posterior wall of the coronary vessel.

h7B3

44. The method of claim 43, wherein the stop mechanism is provided proximate a proximal end of the stent.

Sub
a7

45. The method of claim 1, wherein delivering the stent includes engaging a stop mechanism with at least one interior wall of the coronary vessel.

46. A method of providing direct blood flow between a heart chamber and a coronary vessel, the method comprising:

inserting an expansion device through an anterior wall and a posterior wall of the coronary vessel and into a heart wall;

expanding the expansion device within the heart wall to form a passageway between the heart chamber and the coronary vessel; and

placing a stent within the passageway.

47. The method of claim 46, wherein the stent is collapsible and placing the stent within the passageway includes delivering the stent to the passageway in a collapsed configuration and then expanding the stent within the passageway.

48. The method of claim 47, wherein delivering the stent includes providing an inflatable delivery mechanism onto which the stent is loaded and expanding the stent includes inflating the delivery mechanism.

49. The method of claim 46, wherein the expansion device includes a first expandable mechanism and a second expandable mechanism, and expanding the first

FOR 050-4547860

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N.W.
WASHINGTON, DC 20005
202-408-4000

expandable mechanism forms the passageway and expanding the second expandable mechanism places the stent within the passageway.

50. The method of claim 49, wherein the first and second expandable mechanisms are inflatable mechanisms and the expanding the first and second expandable mechanisms includes inflating the first and second expandable mechanisms.

51. The method of claim 46, further comprising determining the thickness of the heart wall prior to inserting the expansion device, wherein the stent is selected based on the thickness of the heart wall.

52. The method of claim 46, further comprising inserting a guidewire through the anterior wall and the posterior wall of the coronary vessel and through the heart wall prior to inserting the expansion device.

53. The method of claim 52, further comprising the step of inserting a hollow needle through the anterior wall and the posterior wall of the coronary vessel and the heart wall, prior to placing the guidewire.

54. The method of claim 53, wherein the step of inserting the guidewire includes inserting the guidewire through the hollow needle until an end of the guidewire rests in the heart chamber.

55. The method of claim 54, further comprising the step of removing the hollow needle after inserting the guidewire through the hollow needle.

56. The method of claim 53, further comprising the step of measuring a depth of insertion of the hollow needle.

09454-0504

57. The method of claim 53, further comprising avoiding intracardiac structures during insertion of the hollow needle.

58. The method of claim 46, wherein the expansion device is a balloon catheter and inserting the expansion device includes advancing the catheter over the guidewire until a distal balloon at a distal end of the balloon catheter is within the heart wall.

59. The method of claim 58, wherein the balloon catheter includes the distal balloon and a proximal balloon, and inflating the distal balloon forms the passageway and inflating the proximal balloon places the stent within the passageway.

60. The method of claim 59, further comprising, after forming the passageway, deflating the distal balloon and advancing the balloon catheter so that the distal balloon rests in the left ventricle and the proximal balloon is in the passageway.

61. The method of claim 59, wherein the stent is loaded on the proximal balloon in a collapsed configuration and inflating the proximal balloon expands the stent and places the stent within the passageway.

62. The method of claim 58, wherein the stent is placed by a second catheter carrying a second expansion device.

63. The method of claim 62, wherein the second expansion device is a balloon and the balloon is inflated to place the stent.

64. The method of claim 62, wherein the balloon catheter is removed after the passageway is formed and then the second catheter is inserted into the formed passageway to place the stent.

65. The method of claim 46, wherein inserting the expansion device includes inserting the expansion device over a guide device extending between the heart wall and exterior the heart chamber and the coronary vessel.

66. A device for measuring a depth of penetration from an anterior wall of a coronary vessel to a heart chamber, comprising:

- a hollow needle defining a lumen and having a distal end and a proximal end;
- a depth indication mechanism on a surface of the hollow needle; and
- a portion in flow communication with the lumen of the hollow needle so that blood from the heart chamber entering the lumen can be observed.

67. The device of claim 66, further comprising a handle on the proximal end of the needle.

68. The device of claim 66, wherein the depth indication mechanism includes a marker slidably disposed on the needle so as to be configured to move along a longitudinal axis of the needle.

69. The device of claim 66, wherein the marker is configured to abut the anterior wall of the coronary vessel and move along the needle toward the proximal end as the needle penetrates through the coronary vessel and the heart wall and into the heart chamber.

70. The device of claim 68, wherein the marker engages frictionally with the needle.

71. The device of claim 66, wherein the depth indication mechanism includes graduated markings.

81. The device of claim 76, wherein the stop mechanism includes a second expandable portion.

82. The device of claim 81, wherein the second expandable portion is a second balloon.

83. The device of claim 72, wherein the delivery tool includes a sheath.

84. The device of claim 83, wherein the stop mechanism includes an expandable portion on a distal end of the sheath.

85. The device of claim 84, wherein the expandable portion is made of nitinol.

86. The device of claim 84, wherein the expandable portion has a basket-like configuration.

87. A device for placement in a passageway between a heart chamber and a coronary vessel, comprising:

a hollow conduit; and

a plurality of extensions protruding from an end of the conduit.

88. The device of claim 87, wherein the plurality of extensions includes a pair of extensions at opposite sides of the conduit.

094514-0300
F07050-45754860